

Attorney Docket No.: **KBI-0017**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/676,622**
Filing Date: **September 30, 2003**
Page 3

REMARKS

Claims 1-7 are pending in the instant application. Claims 4-7 have been withdrawn from consideration and canceled. Claims 1-3 have been rejected. Claims 1-3 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction

The restriction requirement placing the claims into Groups I and II has been deemed proper and made final. Claims 4-7 are withdrawn from further consideration. Accordingly, the Applicant is canceling claims 4-7 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Rejection of Claims Under 35 U.S.C. §112

Claims 2-3 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, claims 2 and 3 are suggested as being vague and indefinite for reciting "B. pasteurii" and "L. sporogenes", respectively. As supported by the teachings at page 8, lines 22-23, of the specification, Applicant has amended claims 2-3 to spell out "Bacillus pasteurii" and "Lactobacillus sporogenes". Accordingly, it is respectfully requested that this rejection be withdrawn.

III. Rejection of Claims under 35 U.S.C. §102

Claims 1-3 have been rejected under 35 U.S.C. 102(e) as being anticipated by Hiatt (U.S. Patent No. 6,025,152). Claims 2-

Attorney Docket No.: **KBI-0017**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/676,622**
Filing Date: **September 30, 2003**
Page 4

3 have been further rejected under 35 U.S.C. 102(b) as being anticipated by Hiatt. The Examiner suggests that Hiatt teaches compositions comprising bacteria which convert nitrogenous wastes to non-toxic compounds, wherein the bacteria are *B. coagulans* (or *L. sporogenes*) and/or *L. sporogenes*. It is suggested that while the reference does not teach that the composition is used for treating renal failure, the intended use the claimed composition does not patentably distinguish the composition, per se, since such disclosed use is inherent in the reference composition. Applicant respectfully disagrees with this rejection.

Hiatt teaches a mixture of bacteria selected from and limited to bacillus bacteria for the purification of contaminated aqueous bodies, wastewater systems and wastewater streams. In contrast, the instant composition is a selected bacterium which converts nitrogenous waste into non-toxic compounds for use *in vivo*. As indicated in the instant specification at the paragraph bridging pages 11 and 11, the selected bacterium is enterically coated to delivery the bacterium to the gastrointestinal tract. Thus, to clarify the instant composition, Applicant has amended claim 1 to recite the singular form of "bacterium" and indicate that the selected bacterium is enterically coated. Because Hiatt fails to teach or suggest a composition suitable for use *in vivo*, this reference does not anticipate the composition of claim 1, nor does it anticipate the compositions of dependent claims 2-3. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1 and 3 have been rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al. (U.S. Patent No. 6,080,401). Claim 3 has also been rejected under 35 U.S.C. 102(a) as being

Attorney Docket No.: KBI-0017
Inventors: Ranganathan, Natarajan
Serial No.: 10/676,622
Filing Date: September 30, 2003
Page 5

anticipated by Reddy et al. It is suggested that Reddy et al. teach a composition comprising probiotics wherein the bacteria is *L. sporogenes*. It is suggested that while the reference does not teach that the composition is used for treating renal failure, or that the bacterium converts nitrogenous wastes into non-toxic compounds *in vivo*, the intended use the claimed composition does not patentably distinguish the composition, per se, since such disclosed use is inherent in the reference composition. Applicant respectfully disagrees with this rejection.

Reddy et al. teach the use of probiotic bacteria to improve the effects of medicinal preparations. This reference teaches that the combined herbs and probiotics or allopathic and probiotics can be placed into combined dosage units, such as by either capsulating or tableting the combined ingredients (see paragraph bridging columns 12 and 13). However, this reference does not teach or suggest enteric coating to deliver bacteria to the gastrointestinal tract. Accordingly, because this reference does not teach each and every limitation of the amended claims (MPEP 2131), this reference does not anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

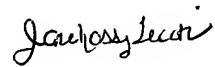
IV. Conclusion

The Applicant believes that the foregoing comprises a full and complete response to the Office Action of record.

Attorney Docket No.: **KBI-0017**
Inventors: **Ranganathan, Natarajan**
Serial No.: **10/676,622**
Filing Date: **September 30, 2003**
Page 6

Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata
Registration No. 32,257

Date: **June 29, 2005**

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515